

PEARSON, J.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

CHILDREN'S HOSPITAL MEDICAL)	
CENTER OF AKRON,)	CASE NO. 4:11cv506
)	
Plaintiff,)	
)	JUDGE BENITA Y. PEARSON
v.)	
)	
YOUNGSTOWN ASSOCIATES IN)	
RADIOLOGY, INC. WELFARE PLAN, <i>et</i>)	
<i>al.</i> ,)	
)	<u>MEMORANDUM OF OPINION AND</u>
Defendants.)	<u>ORDER</u> [Regarding ECF No. 50]

Plaintiff Children's Hospital Medical Center of Akron commenced this action under the Employee Retirement Income Security Act of 1974 ("ERISA"), [29 U.S.C. § 1001 *et seq.*](#), against Defendants Youngstown Associates in Radiology, Inc. Welfare Plan; Youngstown Associates in Radiology, Inc.; and Professional Risk Management (collectively "Defendants"). Plaintiff challenges the administrator's decision to deny insurance coverage for treatment B.W., a minor child, received for leukemia. The Court has reviewed Plaintiff's merits brief, Defendants' oppositions, Plaintiff's reply, the administrative record, and the governing law. For the reasons that follow, the Court dismisses the complaint.

I. Background

A. Parties

Defendant Youngstown Associates in Radiology, Inc. ("YAIR") sponsors and administers the Youngstown Associates in Radiology, Inc. Welfare Plan ("the Plan"). [ECF No. 57 at 2, ¶1](#). The Plan is an ERISA healthcare benefits plan. [*Id.*](#)

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Defendant Professional Risk Management (“PRM”) is a third-party healthcare benefits claims administrator. *Id.* It processes claims for the Plan on behalf of YAIR. *Id.* PRM is an affiliate of Meritain Health, Inc (“Meritain”). *ECF No. 54 at 7 n.2.*

B.W. is a minor child who was diagnosed with Acute Myeloid Leukemia (“AML”) in 2009. *ECF No. 58 at 2, ¶1.* He was admitted to Plaintiff Children’s Hospital Medical Center of Akron for treatment beginning October 6, 2009. *Id.* During treatment, B.W. was insured under the Plan through his mother’s policy with YAIR. *Id. at ¶2.*

B. Facts

On October 7, 2009, Plaintiff admitted B.W. *ECF No. 58 at 3, ¶10.* B.W. was scheduled for chemotherapy. *Id. at ¶12; at 4, ¶17.* He was enrolled in a clinical trial in which he would, in addition to conventional chemotherapy, receive the drug gemtuzumab. *Id. at 3, ¶¶14, 15;* A.R.1656.¹ In order to enroll in the trial, B.W.’s mother signed a consent form provided by Plaintiff. *Id. at ¶14.* B.W. received gemtuzumab on October 14, 2009. *Id.*

On October 30, 2009, coverage under the Plan for B.W.’s treatment was denied. *Id. at 4, ¶17.* The stated reason for the denial of coverage was that the treatment was excluded under the Plan because it was a “clinical trial.” *Id.* On December 15, 2009, B.W. was removed from the trial. *ECF No. 55 at 14.* Thereafter, B.W.’s treatments were covered under the Plan. *See ECF No. 54-1.* During the course of B.W.’s treatment, Plaintiff received payment directly from Defendants for services provided to B.W. *ECF No. 58 at 8, ¶54.*

On April 14, 2010, Plaintiff attempted to appeal the denial of benefits in a letter sent to

¹ “A.R.” refers to the Administrative Record filed under seal. *See ECF No. 32.*

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PRM. [ECF No. 50 at 27](#); A.R. 57. In response to Plaintiff's letter, PRM stated that the appeal had been reviewed and denied. *Id.* It also advised Plaintiff that the Plan contained an anti-assignment clause that barred Plaintiff's appeal. *Id.*; A.R. 98.

On October 5, 2009, B.W.'s mother had signed a document entitled "Assignment of Benefits." [ECF No. 57 at 8, ¶31](#). On August 19, 2010, B.W.'s mother signed another document entitled "Assignment of Insurance Appeal Rights." [ECF No. 54 at 31](#). The document directed Defendants to "allow [Plaintiff] to take any and all actions that we may take as relates to this claim." [ECF No. 8 at 19](#). On August 31, 2010, Plaintiff sent another appeal letter and included a copy of the Assignment of Insurance Appeal Rights. [ECF No. 54 at 32](#). On October 28, 2010, the Meritain Health Appeals Department sent Plaintiff a letter acknowledging receipt of the August 31 letter and noting, "your appeal was deemed an appeal on behalf of the Plan participant." *Id.* The appeal was denied. *Id.*

C. Claims

Plaintiff filed a Complaint as a derivative action pursuant to the executed assignment of appeal rights, seeking benefits it alleges were wrongfully denied pursuant to [29 U.S.C. § 1132\(a\)\(1\)\(B\)](#). [ECF No. 1 at 11; 50 at 15](#).² Plaintiff alleges Defendants arbitrarily and capriciously: (1) denied coverage as experimental, investigational, or research-oriented, [ECF No. 50 at 28](#); (2) deprived it of due process by refusing to give sufficient notice of and an appeal from the denial of B.W.'s claims, [ECF No. 1 at 8; 50 at 23](#); and (3) based the decision on financial

² Plaintiff also relies on an assignment of benefits that was signed by B.W.'s mother on October 5, 2009. [ECF No. 50 at 15](#).

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instead of contractual reasoning, [ECF No. 50 at 30](#). Plaintiff also alleges that Defendants breached a fiduciary duty because they failed to provide sufficient notice and based the decision on financial instead of contractual reasoning. [ECF No. 50 at 15, 23](#). Lastly, Plaintiff asserts a claim for Defendants' failure to comply with Ohio Revised Code § 3923.80. [ECF No. 1 at 10](#).

In the Complaint, Plaintiff alleges Defendants wrongfully denied benefits totaling \$743,304.83. [ECF No. 1 at 13](#). Defendants dispute that amount. PRM included an Accounting of Payments with its brief itemizing claims submitted and payments made. [ECF No. 54-1](#). Defendants also contend that the amount Plaintiff seeks includes services provided after Plan coverage ceased on June 1, 2010.³ [ECF Nos. 53 at 4, n.2; 54 at 28 n.26](#). Plaintiff does not dispute this evidence and it is supported by the record. *See, e.g.*, A.R. 4 (letter stating coverage ceased on June 1, 2010). Thus, it appears as though the only claims at issue are the ones submitted in October through December, 2009, when B.W. was enrolled in the clinical trial. *See ECF No. 54-1*.⁴ Accordingly, the Court considers the decision regarding the claims for treatment that were denied because they involved a clinical trial—gemtuzumab and related treatment.

II. Legal Standard

When an ERISA plan gives the plan administrator discretion in interpreting its terms or

³ According to YAIR, services provided after June 1, 2010 account for \$505,086.19 of the \$743,304.83 Plaintiff seeks to recover. [ECF No. 53 at 4 n.2](#).

⁴ For example, Plaintiff alleges Defendants denied coverage for surgery B.W. received prior to the start of the clinical trial that was not related to the clinical trial. [ECF No. 58 at 4, ¶18](#). Plaintiff does not contend that this claim is still outstanding, only that it was originally denied. As noted, Plaintiff does not respond to PRM's accounting of claims paid that would indicate this claim has been paid. *See ECF No. 54-1* (noting "partial payment" for claims submitted October 6, 2009-November 6, 2009).

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making benefits determinations, as the parties agree this Plan does, a court reviews the administrator's decision under the deferential arbitrary-and-capricious standard of review.

Farhner v. United Transp. Union Discipline Income Prot. Program, 645 F.3d 338, 342 (6th Cir. 2011); Wilkins v. Baptist Healthcare Sys., Inc., 150 F.3d 609, 613 (6th Cir. 1998). Under the arbitrary and capricious standard of review, the court must uphold the administrator's decision if the administrator's interpretation of the plan's provisions is "reasonable" or "rational." *Price v. Bd. of Tr. of Ind. Laborer's Pension Fund, 632 F.3d 288, 295 (6th Cir. 2011)* (quoting *Kovach v. Zurich Am. Ins. Co., 587 F.3d 323, 328 (6th Cir. 2009)*); *Schwalm v. Guardian Life Ins. Co. of Am., 626 F.3d 299, 308 (6th Cir. 2010)*). This standard of review does not require courts to "rubber stamp[]" a plan administrator's decision, however. *Id. at 308*. "A court must review the quantity and quality of the medical evidence on each side." *Id.* (quoting *Evans v. UnumProvident Corp., 434 F. 3d 866, 876 (6th Cir. 2006)*). The decision must be upheld if it results from "a deliberate principled reasoning process" and is supported by "substantial evidence." *Id.* (quoting *Baker v. United Mine Workers of Am. Health & Ret. Funds, 929 F. 2d 1140, 1144 (6th Cir. 1991)*). The plaintiff bears the burden of proving the plan administrator's decision was arbitrary and capricious. *Farhner, 645 F.3d at 343.*

III. Discussion

The parties dispute whether Plaintiff has standing to bring this action. The Court need not resolve that issue, however, because it finds that even if Plaintiff properly maintains its claims, the claims fail on the merits.

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A. Denial of Plan Benefits Under the “Experimental” Clause

The Plan Administrator denied coverage because it found B.W.’s treatment was excluded under the Plan. [ECF No. 54 at 8](#). The Plan excludes from coverage “[e]xpenses for treatment, procedures, devices, drugs or medicines which are determined to be Experimental and/or Investigational.” [Id.](#); A.R. 1941. Plaintiff “does not dispute the Plan’s right to exclude payment for experimental or investigational treatments and medicines,” but argues that B.W.’s treatment was not experimental or investigational. [ECF No. 55 at 15](#). In support, Plaintiff relies on a letter from B.W.’s physician stating that it is standard practice for a child with a similar diagnosis to be enrolled in a clinical trial. [Id.](#) Defendants point out that the Plan defines what “experimental” is and that the Plan Administrator is tasked with making that determination. [ECF No. 54 at 27](#).

The Plan reads,

Experimental and/or Investigational means services, supplies, care and treatment which do not constitute accepted and appropriate medical practice considering the facts and circumstances of the case and by the generally accepted standards of a reasonably substantial, qualified, responsible, relevant segment of the appropriate medical community or government oversight agencies at the time services were rendered, as determined by the Plan Administrator as set forth below.

.... [t]he Plan Administrator will be guided by the following principles to determine whether a proposed treatment is deemed to be Experimental and/or Investigational:

(1) if the drug or device cannot be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and approval for marketing has not been given at the time the drug or device is furnished, then it is deemed to be Experimental and/or Investigational; or

(2) *if the drug, device, medical treatment or procedure, or the patient informed consent document utilized with the drug, device, treatment or procedure, was reviewed and approved by the treating facility’s Institutional Review Board or other body serving a similar function, or if federal law requires such review or approval, then it is deemed to be Experimental and/or Investigational; or*

(3) *if Reliable Evidence shows that the drug, device, medical treatment or*

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procedure is the subject of on-going phase I or phase II clinical trials, or *is the subject of the research, experimental, study, investigational or other arm of on-going phase III clinical trials*, or is otherwise under study to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis, then it is deemed to be Experimental and/or Investigational; or

(4) if Reliable Evidence shows that the prevailing opinion among experts regarding the drug, device, medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated dose, its toxicity, its safety, its efficacy or its efficacy as compared with a standard means of treatment or diagnosis, then it is deemed to be Experimental and/or Investigational.

A.R. 1914-1915 (emphasis added). The Plan goes on to define “Reliable Evidence” as “published reports and articles . . . ; or the written informed consent used by the treating facility or by another facility studying substantially the same drug, device, medical treatment or procedure.” *Id.* at 1915.

Defendants assert the written informed consent form signed by B.W.’s parents describing the treatment as “research,” “a clinical trial,” and “experimental” constitutes reliable evidence that the clinical treatment was experimental. [ECF No. 57 at 39, ¶76](#) (citing the informed consent, A.R. 1790-1822). They point out the consent form bears the stamp of Plaintiff’s Institutional Review Board. [ECF No. 53 at 10](#). A review of the informed consent supports Defendants’ statements. *See, e.g.*, A.R. at 1790 (“This study is called a clinical trial. A clinical trial is a research study involving treatment of a disease in human patients.”) (“Clinical trials include only people who choose to take part. You have a choice between a standard treatment for AML and this clinical trial.”); at 1791 (“Researchers want to know if they can improve the cure rate for AML by adding a new chemotherapy drug, called gemtuzumab, to the standard chemotherapy treatments. Gemtuzumab is a new experimental treatment.”).

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Plaintiff argues that, “as the informed consent forms show, dosage, safety, and efficacy for [g]emtuzumab had all been determined prior to the initiation of this study in Phase I and Phase II clinical trials.” [ECF No. 55 at 17](#). Plaintiff cites A.R. at 0050-51, which is not the informed consent but a reviewing physician’s description of the treatment. In any event, Plaintiff’s argument is misplaced. For example, Plaintiff goes on to explain that, although B.W. was enrolled in a Phase III trial, the goal of that trial conflicts with the portion of the Plan that relates to Phase III trials because the goal was *not* to determine the maximum tolerated dose, toxicity, safety, and efficacy of gemtuzumab, but to track and share B.W.’s “treatment and outcomes.” [ECF No. 55 at 16-17](#). Regardless, the Plan sections appear in the disjunctive. Thus, Section (3) includes, in the disjunctive, whether the drug or treatment “is the subject of the research, experimental, study, investigational or other arm of on-going phase III clinical trials, or is otherwise under study to determine its maximum tolerated dose, its toxicity . . .” (Emphasis added.) Plaintiff does not offer evidence that shows the language in the informed consent is in conflict with this section. In fact, Plaintiff’s description of the clinical trial appears to fit squarely within the above description in section (3), as the subject of research, study, investigation or other arm of an on-going phase III clinical trial.

The informed consent goes on to describe the trial:

WHAT WILL HAPPEN ON THIS STUDY THAT IS RESEARCH?

Random Assignment

Subjects (people participating in the study) will receive one of two different treatment plans. The treatment plan they receive is decided by a process called randomization. Randomization means that the treatment is assigned based on chance. It is a lot like flipping a coin, except that it is done by computer to make sure that there are about the same number of people on each treatment plan of the study. The randomization process is described in the COG Family Handbook for

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Children with Cancer.

In this study, randomization takes place at the beginning of the study. Subjects will be assigned to either Arm A, the current standard therapy, or Arm B, which is considered the experimental arm. Arm B uses the current standard therapy in combination with gemtuzumab. Gemtuzumab has been given to children with AML before but it has not yet been compared to the current therapy to see if it improves outcome.

A.R. 1792. *See also id.* at 1798 (“Risks of Study. If you are randomized to experimental Arm B, the use of gemtuzumab may cause more complications when combined with the use of standard chemotherapy treatment for AML.”). The Court finds it is a reasonable interpretation of the informed consent that the treatment involves an experimental clinical trial.

Plaintiff argues that even if the administration of gemtuzumab was experimental, the treatment B.W. received, minus the gemtuzumab, was medically necessary and should, therefore, be covered by the Plan. [ECF No. 55 at 15](#). Defendants, however, identify the portion of the Plan that clearly states,

Expenses for drugs, devices, services, medical treatments or procedures related to an Experimental and/or Investigational treatment (“Related Services[“”]) and complications from an Experimental and/or Investigational treatment and their Related Services are excluded from coverage, even if such complications and Related Services would be covered in the absence of the Experimental and/or Investigational treatment.

A.R.1915; [ECF No. 54 at 27-28](#). The Court finds that under the plain language of the Plan, medically necessary treatment that would normally be covered under the Plan, *i.e.* the non-gemtuzumab drugs, were administered pursuant to the clinical trial, were related to the trial and, thus, excluded from coverage.

In sum, despite Plaintiff’s assertion that the clinical trial was the accepted practice for a

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child with B.W.'s diagnosis, the Plan Administrator's denial of the claim, based on the plain language of the Plan, is not irrational, arbitrary or capricious. *See Farhner, 645 F.3d at 342.*

B. Due Process per 29 U.S.C. § 1133 and 29 C.F.R. § 2560.503-1

Pursuant to [29 U.S.C. § 1133](#), all ERISA employee benefit plans must provide adequate notice in writing of the denial of claims. The notification must also afford a reasonable opportunity to any participant for a full and fair review of the denial. *Id.* The Code of Federal Regulations, promulgated under [29 U.S.C. § 1133](#), also requires a plan administrator to provide notice of the denial of a claim. [29 C.F.R. § 2560.503-1\(f\)](#). The denial notice must include: (1) the specific reasons for the adverse determination; (2) reference to the specific plan provision on which the determination is based; (3) a description of any additional material or information necessary for the claimant to perfect a claim and an explanation of why the material is necessary, and; (4) a description of the plan's review procedures and applicable time limits. [29 C.F.R. § 2560.503-1\(g\)\(1\)\(i-iv\).](#)

Plaintiff argues that PRM failed to meet the notice requirements described above. [ECF No. 50 at 24](#). Plaintiff also contends PRM failed to provide a reasonable opportunity for a full and fair review after the denial of benefits. [Id. at 27](#). PRM rejoins that (1) Plaintiff did not have rights to the initial notice because they had not yet purportedly been assigned any rights; and (2) the review procedure was appropriate.⁵ [ECF No. 54 at 31-32](#).

⁵ Defendants challenge the validity of the Assignment of Insurance Appeal Rights executed on August 19, 2010 in light of the Plan's anti-assignment clause. [ECF Nos. 53 at 14; 54 at 7](#). For purposes of this opinion, the Court considers, without deciding, that the assignment is valid, enforceable, and broad enough in scope to encompass this claim.

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1. Initial Notice

Plaintiff argues that it “did not receive adequate notice of the denial of B.W.’s claims.” [ECF No. 50 at 24](#). It contends that PRM did not provide Plaintiff with sufficient reasons for the denial, did not explain to Plaintiff what additional information could be provided in order to perfect the claim and obtain coverage for B.W.’s treatment, and did not include a description of the Plan’s review procedures. [Id. at 25-26](#). In support, Plaintiff cites to portions of the record that include the “Explanation of Benefits” that PRM sent to Plaintiff in December 2009, shortly after B.W.’s treatment. [Id.](#) (citing A.R. 507, 632, 71).

PRM indicates that [29 U.S.C. § 1133\(1\)-\(2\)](#) requires adequate notice to “any participant or beneficiary.” [ECF No. 54 at 31](#). PRM asserts that “if Plaintiff is going to assert any ERISA due process rights, Plaintiff must assert the assignors’ due process rights. Plaintiff has no ERISA due process rights of its own to assert.” [Id.](#) PRM contends that Plaintiff only argues that it, and not B.W.’s mother, did not receive proper notice. [Id.](#)

Plaintiff does not respond to this argument. On October 5, 2009, B.W.’s mother assigned to Plaintiff “all my rights to any and all medical insurance benefits to which I am or may be entitled by any private or public payor.” [ECF No. 47 at 2](#). This document does not purport to assign statutory ERISA rights to Plaintiff. To the extent the second assignment of benefits, on August 19, 2010, may have assigned additional rights to Plaintiff, these rights were purportedly assigned after the explanation of benefits were sent.⁶ Therefore, Plaintiff did not have rights to

⁶ Plaintiff, in reply, argues for the first time that B.W.’s treatment was “urgent,” requiring PRM to comply with [C.F.R. § 2560.503-1\(i\)\(2\)\(i\)](#). [ECF No. 55 at 18](#). Plaintiff does not allege PRM violated this provision, but only that PRM does not allege that it complied with this

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process afforded under [29 U.S.C. § 1133](#) or [29 C.F.R. § 2560.503-1\(h\)](#).

2. Full and Fair Review

Plaintiff asserts that it was not provided a reasonable opportunity for a full and fair review after the denial of benefits. [ECF No. 50 at 27](#). It argues, “Children’s attorney wrote to PRM/Meritain on April 14, 2010 to appeal the denial of coverage and to request additional information.” *Id.* (citing A.R. 0057). Plaintiff goes on to complain of PRM’ actions regarding Plaintiff’s attempt to challenge the denial of benefits following the initial contact in April 2010 through August 2010. *Id.* For the reasons explained above, Plaintiff did not have rights to process afforded under [29 U.S.C. § 1133](#) or [29 C.F.R. § 2560.503-1\(h\)](#) during this time.

On August 19, 2010, B.W.’s parents signed an “Assignment of Insurance Appeal Rights” in which it directed Plaintiff “to take any and all actions that we may take as relates to this claim.” A.R. 47. On August 31, 2010, pursuant to the assignment, Plaintiff appealed the denial of benefits. A.R. 46. On October 28, 2010, PRM sent a letter to Plaintiff denying the appeal. A.R. 29-30. PRM asserted that it deemed Plaintiff’s appeal to be “an appeal on behalf of the Plan participant.” A.R. 29. The letter set out enumerated reasons for denying the appeal that, on the surface, comport with the provisions in the Plan and [29 C.F.R. § 2560.503-1\(h\)](#).

Plaintiff argues that “it was never given access to the Plan Document, despite PRM/Meritain’s eventual assessment that Children’s was appealing on behalf of the Plan participant.” [ECF No. 50 at 27](#). Plaintiff also complains that it never received information about

provision. *See id.* (“nowhere in its brief does PRM claim to have provided B.W.’s parents . . .”; “Likewise, PRM does not claim that B.W.’s parents were supplied with . . .”).

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the internal appellate process. *Id.* Plaintiff, however, does not allege that it requested a copy of the Plan at the time of the appeal or information about the internal appeals process, and the citations to the record provided by Plaintiff are not relevant to its argument. *See id.* (citing A.R. 26, 98 (communications prior to the August 2010 assignment of benefits in which PRM informed Plaintiff it is not entitled to a copy of the Plan); 2-3 (denial letter); 46 (Plaintiff's letter of appeal)).

Plaintiff also argues that clear language in the Plan and [29 C.F.R. § 2560.503-1\(h\)\(3\)\(iii\)](#) directs the Plan fiduciary to consult with a health care professional when considering an appeal in cases involving "medical judgment." [ECF No. 55 at 18](#); *see also* A.R. 1915 (Plan). PRM retorts that the Plan fiduciary did not need to consult with a health care professional because the decision was based on "contractual language." [ECF No. 57 at 16, ¶81](#). In support, PRM cites section (a)(ii) of the Plan. *Id.* (citing A.R. 1949). The Plan, at the cited page or elsewhere, does not provide that the Plan fiduciary need not consult with a health care professional. Instead, the relevant section reads,

The appropriate named fiduciary of the Plan will consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment before making a decision on review of any adverse initial benefit determination based in whole or in part on a medical judgment, including determinations with regard to whether a particular treatment, drug or other item is Experimental, Investigational or not Medically Necessary or appropriate. The professional engaged for purposes of a consultation in the preceding sentence shall be an individual who was neither an individual who was consulted in connection with the adverse initial benefit determination that is the subject of the appeal, nor the subordinate of any such individual.

A.R. 1915. Thus, the Court finds the Plan fiduciary was required to consult with a health care professional.

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PRM submits that it did consult with two health care professionals from AllMed. [ECF No. 57 at 16, ¶ 82](#). The Court notes these health care professionals were consulted in November and December, 2009, and not as a result of Plaintiff's letter of appeal in 2010. *See* A.R. 50-52. Presumably, the health care professionals were consulted pursuant to the appeal by B.W.'s mother. As Plaintiff states, B.W.'s mother and his physician, Dr. Savelli, had, after the initial denial of benefits in October 2009, "question[ed] and appeal[ed] PRM's adverse determination. Those appeal attempts began as early as October 30, 2009 and continue through December 15, 2009 when B.W. was removed from the study." [ECF No. 55 at 14](#) (internal record citations omitted).

Turning to the substance of the health care professionals' opinions, Plaintiff argues that the opinions support its argument that the treatment was not "experimental" and, therefore, covered by the Plan. [ECF No. 50 at 28-29](#). Plaintiffs submit that "Dr. Savelli and both of the reviewing doctors for AllMed found that B.W.'s treatment was the standard of care for AML. They also all noted that B.W.'s treatment was the accepted and appropriate medical practice for similarly situated children in pediatric oncology." [Id.](#) Although both AllMed reviewers opined that the treatment is the "standard of care" for pediatric patients, and one reviewer asserted that the treatment is not experimental (the other reviewer asserted the treatment is experimental), both reviewers stated that B.W. was part of a Phase III clinical trial and had been placed on the "experimental arm" of that trial.⁷ A.R. 50-52. The fact that a clinical trial is "standard" for

⁷ The letter from B.W.'s physician, Dr. Savelli, also recited it was standard to enroll a child with B.W.'s illness in a clinical trial. Additionally, she acknowledged gemtuzumab is "experimental" and elaborated on the investigatory purposes of the trial. [ECF No. 8 at 20-21](#).

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pediatric patients does not mean that it cannot also be experimental or investigatory. Even Meritain's representative acknowledged as much in an email to a YAIR representative, on October 15, 2009:

99% of the time young children with this type of diagnosis are placed on experimental/observational treatments. If this was the case for [B.W.], we need to make sure prior to services and claims incurred. This is to protect the plan as well as the family. We do not want to see them proceed with a treatment that is identified after the fact that it is not a covered benefit.

A.R. 1617-1618.⁸

The issue is not whether B.W.'s treatment with gemtuzumab was standard, or good care for his disease, but whether B.W.'s treatment fell within the Plan definition of experimental or observational as determined by the Plan Administrator. Based on the record, the Plan Administrator's decision that B.W.'s treatment was experimental was not arbitrary or capricious.

Even if the appeals process amounted to a procedural violation, the proper remedy for the procedural violation would be to permit Plaintiff to present additional evidence before the Court.

See Univ. Hosp. of Cleveland v. S. Lorain Merchants Ass'n Health & Welfare Benefit Plan & Trust, 441 F.3d 430, 434 (6th Cir. 2006) (citing *VanderKlok v. Provident Life & Accident Ins. Co.*, 956 F.2d 610, 617 (6th Cir. 1992)). Plaintiff has already presented additional information, to no avail. *See ECF No. 49* (Sealed Supplemental Record). It does not claim to have other, helpful information that would circumvent the clear language in the Plan and it is difficult to imagine any that would. The Court is obligated to uphold the eligibility determination if it is

⁸ Moreover, as YAIR notes, "the email indicates an interpretation of plan language already well established before the first of the hospital's bills for BW's treatment related to the Gemtuz[u]mab clinical trial was sent." [ECF No. 53 at 11](#).

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“rational in light of the plan’s provisions.” *Criss v. Sheet Metal Workers Nat. Pension Fund, No. 5:05-CV-942, 2006 WL 3628081, at *4* (N.D. Ohio Dec. 11, 2006) (quoting *Yeager v. Reliance Standard Life Ins. Co.*, 88 F.3d 376, 381 (6th Cir.1996)). As previously stated, the decision was rational in light of the Plan’s provisions.

C. Conflict of Interest

The parties agree that a conflict of interest exists in the case because YAIR is the Plan Administrator and the Plan Sponsor. [ECF Nos. 56 at 10, ¶11; 50 at 31](#). When a conflict of interest is present, the standard of review does not change—it is a factor to be considered.

Metropolitan Life Ins. Co. v. Glenn, 554 U.S. 105, 108 (2008); *Schwalm*, 626 F. 3d at 311-312.

Plaintiff argues that the conflict in the instant case constitutes reversible error. [ECF No. 50 at 32](#). It cites an email string between YAIR employee Judi Miles and a Meritain employee in which the two discuss coverage of B.W.’s claims. [Id. at 32](#). It alleges that, when Miles discovered the stop-loss carrier would not cover B.W.’s claim, she “changed her position.” [Id. at 33](#). Thus, Plaintiff argues, “[o]nce YAIR determined that it, and not the stop loss carrier, would be responsible for paying the shortfall in B.W.’s treatment, it denied his claims.” [Id. at 32](#).

As an initial matter, the Court notes that Miles is not the Plan Administrator, but YAIR’s office manager. [ECF No. 56 at 5, ¶20](#). Moreover, the email communications do not definitively support Plaintiff’s allegations. The emails reveal that Miles expressed confusion about why B.W.’s treatment, excluding the gemtuzumab, was not covered under the Plan. *See* A.R. 1606-1607. The Meritain employee, Stephanie Turney, responded, “[p]lease refer to #8 in the Exclusions of the SPD. It is our policy to deny all [experimental-] related coverage.” A.R. at

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1605. The email adds, “[s]hould you want us to cover all treatment with the exception of the chemotherapy drug then we can do so, however I cannot guarantee that the stop loss carrier will accept the risk.” *Id.* Miles asked for a meeting with the case manager to discuss the coverage. *Id.* Turney set up the meeting and further directed Miles to review language in the Plan. *See* A.R. at 1604 (“Tatia Sheppard, who is the supervisor for the Medical management department is more than willing to discuss as this is never a good situation for clients/members when clinical trials come into play.”); (“I also would need you to review pages 13 & 14 on the plan document where it discusses clinical trials.”). The fact that Turney also conveyed to Miles that “I have also discussed with the stop loss carrier and they advised that they follow the exclusions and coverage as set forth within the SPD” does not clearly indicate that the decision to deny the claim was motivated by the conflict. The communications refer to the Plan language that clearly excludes coverage for experimental and related treatment, in response to Miles’ question about why the related treatment was not covered. Thus, it cannot be said, as Plaintiff alleges, that the record establishes that, “[a]s an employee of YAIR [], Ms. Miles decision evidenced a conflict between her duty to the Plan beneficiary and the financial interests of the Plan.” [ECF No. 50 at 33](#). After considering the conflict of interest in the present case, the Court finds that it does not weigh in favor of a finding that the decision to deny coverage was arbitrary or capricious.

D. Breach of Fiduciary Duty

Plaintiff argues Defendants breached their fiduciary duty in denying B.W. coverage based on financial and not contractual reasoning. [ECF No. 50 at 15](#). Plaintiff’s arguments here are essentially the same arguments advanced regarding conflict of interest. *See id. at 31*.

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Plaintiff also alleges Defendants failed to consider independent medical opinions in denying coverage. [ECF No. 50 at 31](#). This, too, was considered by the Court, *supra*.

Moreover, YAIR argues that when “a breach of fiduciary duty claim asserts and is essentially a repackaged claim for benefits, such a breach of fiduciary duty claim does not lie.” [ECF No. 53 at 20](#) (citing *Wilkins*, 150 F. 3d at 615); *see also Gore v. El Paso Energy Corp. Long Term Disability Plan*, 477 F.3d 833 838-842 (6th Cir. 2007) (discussing and collecting cases); [Moss v. Unum Life Ins. Co.](#), 495 Fed.App’x 583, 589-90 (6th Cir. 2012) (*Gore* permits a claim for denial of benefits and breach of fiduciary duty when the plaintiff sought recovery of benefits according to the plan terms as they were misrepresented to him by the defendant, rather than according to the actual terms of the plan—accordingly, no cause of action for breach of fiduciary duty when the plaintiff does not show any “inaccurate, deceptive or misleading information.”). Plaintiff does not respond to this argument. It does not allege Defendants misrepresented the terms of the Plan. The remedy it seeks is “an order declaring that Plaintiff’s claims were not excludable under the definition of investigational/experimental care in the Plan and reversing Defendant[s’] claims denials.” [ECF No. 1 at 13](#). The Court finds that, because Plaintiff’s breach of fiduciary duty is essentially a claim for benefits, the claim is not permitted. *See Gore*, 477 F.833, 841.

E. Ohio Claim

Finally, Plaintiff asserts a claim pursuant to [Ohio Revised Code § 3923.80](#). [ECF No. 1 at 10](#). Defendants, in their briefs, point out that Plaintiff has abandoned this claim, most likely because ERISA preempts it. [ECF Nos. 54 at 34; 56 at 10](#). Plaintiff does not respond to this

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argument or mention [R.C. § 3923.80](#) in its brief in reply. Accordingly, the Court finds that Plaintiff has abandoned its claim based on [R.C. § 3923.80](#) or, in the alternative, finds that the claim is preempted.

IV. Conclusion

The Court finds that the Plan Administrator did not arbitrarily and capriciously deny coverage for B.W.'s treatment in light of the plain language in the Plan. Accordingly, the Court dismisses Plaintiff's Complaint.

IT IS SO ORDERED.

March 31, 2014
Date

/s/ Benita Y. Pearson
Benita Y. Pearson
United States District Judge